

04 agent, the container of clearant agent and the container of infiltrating medium, in order to automatically and sequentially process the sample.

REMARKS

Claims 1-6 are amended herewith. Claims 23-32 are newly added herewith. Claims 1-6 and 23-32 are in the application for consideration. A marked up version of the amended claims and the amended portions of the specification, to show all the changes, are attached hereto on pages separate from the amendment in accordance with 37 CFR 1.121(b), (c). No new matter has been added to the application by the amendments made. Further, an appendix of the currently pending claims is provided.

Specification

In paragraph two, the Office Action requested that the specification be amended to cancel the computer program listing currently appearing in the appendix, to file a computer program listing appendix on compact disc and to insert an appropriate reference in the specification regarding the computer program listing appendix on compact disc. Applicants hereby submit a compact disc with the computer program listing appendix. Applicants further amend the specification where it is believed appropriate.

Rejections based the Muller reference

In paragraph six of the Office Action, claims 1 and 2 were rejected as being unpatentable over Muller et al. (EP 0 508 568). In paragraph seven, claims 3-6 were rejected as being unpatentable over Muller et al. in view of Kinney et al. (U.S. Patent No.

4,001,460). The Office Action states that the Muller reference discloses an apparatus which is capable of reprocessing a specimen from an infiltrating medium to an aqueous fluid. The Office Action states that the Muller reference does not disclose the reprocessing as claimed. However, the Office Action states that it would have been obvious to modify the Muller reference, which teaches processing of the sample, to reprocess samples. The Office Action further states that Kinney et al. disclose an automated system for processing a tissue sample, controlling the flow with respect to the use of purge clearant (9) and purge dehydrant (10).

Applicants amend the claims to clarify the aspect of the invention presently claimed. Claim 1 recites “a control device having a processor and a memory device, the processor controlling . . . the fluid flow selector to connect any of the containers to the processing chamber in any sequence” “thereby automatically and sequentially processing and reprocessing the specimen.” Applicants believe that the claims, as currently drafted, distinguish over the cited art for several reasons. First, the prior art does not teach or suggest the automatic reprocessing of a tissue sample. In the Supplemental Response To Office Action Dated July 17, 2001, Applicants submitted the Declaration of Thomas Kennedy which detailed the need for reprocessing a tissue sample and the failure of the prior art to provide an automated tissue reprocessing machine.

Second, the prior art fails to teach or suggest a single apparatus which automatically and sequentially processes and reprocesses a tissue sample. Instead, the cited art teaches an automated apparatus to process a tissue sample and a manual process to reprocess the tissue sample. By contrast, the present invention, as claimed, recites an apparatus for automating both processes. This single apparatus saves valuable laboratory

space by enabling the processing and reprocessing in a housing which is no bigger than a typical machine for processing a tissue sample. Further, this single apparatus saves considerable money, either in terms of not requiring the purchase of two machines one for processing and another for reprocessing or, alternatively, requiring an operator to manually reprocess the sample.

Third, the prior art fails to teach a “a control device having a processor and a memory device, the processor controlling . . . the fluid flow selector to connect any of the containers to the processing chamber in any sequence” as recited in amended claim 1. Prior art tissue processing machines, as typified by the cited Kinney reference, are locked into a predefined sequence of connecting to containers for processing. For example, in the Kinney reference, column 4 lists the containers for the device. The first eight containers contain solution for processing. The last two containers (containers 9 and 10) contain solution which are for the purpose of cleaning the processing chamber after the tissue has been removed. See col. 4, lines 19-24 (“Further solutions such as Xylene and alcohol will be contained in containers nine and ten for purposes of cleaning processing chamber 12 following a completed processing sequence and withdrawal of processed tissue specimens from chamber 12.”) The Kinney reference, using a rotary valve, steps through a predefined sequence of containers 1-8, sequentially connecting each of the containers to the processing chamber. There is only one programmed sequence and no other sequence is available, as discussed in the following excerpt from the Kinney reference:

Under an automatic mode of operation of the processor, solution pump-in, pump-out and stepping to the next solution step takes place in the appropriate preselected time sequence, throughout the designated processing solution numbers 1 through 10 and including the two paraffin steps hereinbefore

described.

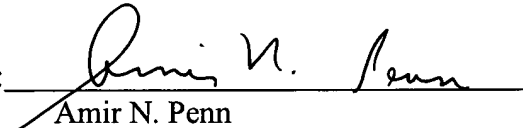
Col. 9, lines 13-18. By contrast, the connections of the containers to the processing chamber are not fixed to a single sequence. In particular, the control device may connect the containers to the processing chamber in any sequence, thus allowed for both processing and reprocessing of the specimen. This flexibility of connecting any containers to the processing chamber is not taught or suggested by the cited references. Thus, the claims as currently written patentably distinguish over the cited references.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the presently pending claims in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

Respectfully submitted,

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APPENDIX UNDER 37 CFR 1.121(b)

Please insert at page 1, line 6 as follows:

COMPUTER PROGRAM LISTING

A computer program listing appendix has been submitted with the present application on a compact disc. The computer program listing appendix on the compact disc is hereby incorporated by reference in its entirety. The total number of compact discs including duplicates is 2. The computer program listing appendix lists the software having a set of instructions for reprocessing of a specimen. The software is written in Z-80 assembly programming language and is executed on the Hitachi HD-64180 (Z-80) microcontroller.

Please amend page 11, line 15 - page 12, line 5 lines as follows:

The Operating Module 12 further includes a control device 28. The control device, in one embodiment, may be a general purpose computer. This control device 28 automatically controls and sequences the operation of the heaters, motors, pumps and valves, which are controlled via cables. The control device 28 includes, in a preferred embodiment, a processor 54, and in particular, a Hitachi HD-64180 (Z-80) microcontroller. The control device may also include an electro-mechanical timer, an embedded microprocessor circuit, a programmable logic controller, an external computer, or any combination of the above. The control device 28, in one embodiment, contains memory 56 or other computer readable storage medium, including both random access memory (RAM) 58 and read only memory (ROM) 60 in the form of an erasable programmable read only memory (EPROM). The EPROM contains the system operating

program and the text and screen formats for the display. Referring to [Appendix A] the computer program listing on a compact disc and incorporated herein by reference, there is listed the software having a set of instructions for reprocessing of a specimen. The software is written in Z-80 assembly programming language and is executed on the Hitachi HD-64180 (Z-80) microcontroller.

Please cancel without prejudice page 24, line 1 – page 42, line 56.

APPENDIX UNDER 37 CFR 1.121(c)

1. (Twice Amended) An apparatus for automatically processing a specimen from aqueous fluid to an infiltrating medium and reprocessing [a] the specimen from [a] the infiltrating medium to [a] the aqueous fluid comprising in combination:

a processing chamber for holding a specimen, said chamber comprising a sealable space for containing various liquids used, and conduits that connect the chamber to liquid containing containers;

a fluid flow selector [means] for [regulating flow of] selecting a fluid to flow to the processing chamber;

a pressure regulator [means] for regulating pressure in the processing chamber, the pressure regulator comprising at least one pressure sensor, the pressure sensor being in fluid communication with the processing chamber;

a temperature regulator [means] for regulating temperature in the processing chamber, the temperature regulator comprising at least one temperature sensor, the temperature sensor being in thermal communication with the processing chamber;

at least one container of infiltrating medium, at least one container of a clearant agent, at least one container of a dehydrant agent and at least one container of an aqueous fluid, the containers of clearant, dehydrant and aqueous fluid being connected to the processing chamber via [means for regulating flow of fluid to the processing chamber] the fluid flow selector; and

a control device having a processor and a memory device, the processor controlling:

the [means for regulating flow of] fluid flow selector to connect any of the

containers to the processing chamber in any sequence,

· the [means for regulating] pressure regulator [in the processing chamber], and

· the [means for regulating] temperature regulator [in the processing chamber],

thereby [in order to] automatically and sequentially [connect the processing chamber with the container of clearant agent, the container of dehydrant agent and the container of aqueous solution in order to reprocess the specimen and in order to automatically and sequentially regulate temperature and pressure of the processing chamber while the processing chamber is sequentially connected with the container of clearant agent, the container of dehydrant agent and the container of aqueous solution] processing and reprocessing the specimen.

2. (Amended) The apparatus of claim 1 wherein [means for regulating flow of] the fluid flow selector includes [a] at least one rotary valve and wherein the processor selects the containers of clearant, dehydrant or aqueous fluid by setting the rotary valve.

3. (Amended) The apparatus of claim 1 [further comprising:
at least one] wherein the container of [an] infiltrating medium [being] is connected to the processing chamber by a second valve and wherein the processor controls the second valve.

4. (Amended) The apparatus of claim 3 wherein the processor further controls the [means for regulating flow of] fluid flow selector and the second valve in order to automatically and sequentially, after [the] connection to the container of aqueous

fluid, connect the processing chamber with the container of dehydrant agent, the container of clearant and the container of infiltrating medium in order to process the specimen.

5. (Amended) The apparatus of claim 1 further comprising a container of purge dehydrant for cleaning the processing chamber of clearant, the container of purge dehydrant being connected to the processing chamber by the [means for regulating flow of] fluid flow selector, the processor controlling the [means for regulating flow of] fluid flow selector in order to automatically and sequentially connect the processing chamber with the container of clearant agent, the container of purge dehydrant, the container of dehydrant agent and the container of aqueous solution in order to reprocess the specimen.

6. (Amended) The apparatus of claim 5 further comprising a container of purge clearant for cleaning the processing chamber of infiltrating medium, the container of purge clearant being connected to the processing chamber by the [means for regulating flow of] fluid flow selector, the processor controlling the [means for regulating flow of] fluid flow selector in order to automatically and sequentially connect the processing chamber with the container of purge clearant, the container of clearant agent, the container of purge dehydrant, the container of dehydrant agent and the container of aqueous solution in order to reprocess the specimen.

23. (New claim) An apparatus for automatically reprocessing a specimen from an infiltrating medium to an aqueous fluid comprising in combination:

a processing chamber for holding a specimen, said chamber comprising a sealable space for containing various liquids used, and conduits that connect the chamber to liquid containing containers;

a fluid flow selector for selecting the fluid to flow to the processing chamber;

at least one container of a clearant agent;

at least one container of contaminated dehydrant agent;

at least one container of a dehydrant agent, the contaminated dehydrant agent being contaminated with the clearant agent more than the dehydrant agent;

at least one container of an aqueous fluid, the containers of clearant, contaminated dehydrant, dehydrant and aqueous fluid being connected to the processing chamber via the fluid flow selector; and

a control device controlling the fluid flow selector in order to automatically and sequentially connect the processing chamber with the container of clearant agent, the container of contaminated dehydrant agent, the container of dehydrant agent and the container of aqueous solution in order to reprocess the specimen.

24. (New claim) The apparatus of claim 23, further comprising

at least one container of contaminated clearant agent, the contaminated clearant agent being contaminated with the infiltrating medium more than the clearant agent,

wherein the at least one container of contaminated clearant agent is connected to the processing chamber via the fluid flow selector, and

wherein the control device controls the fluid flow selector in order to automatically and sequentially connect the processing chamber with the container of

contaminated clearant agent, clearant agent, the container of contaminated dehydrant agent, the container of dehydrant agent and the container of aqueous solution in order to reprocess the specimen.

25. (New claim) The apparatus of claim 24, wherein the contaminated clearant agent is used to clean the processing chamber of infiltrating medium.

26. (New claim) The apparatus of claim 25, wherein the contaminated clearant agent is purge clearant.

27. (New claim) The apparatus of claim 25, wherein the contaminated dehydrant agent is used to clean the processing chamber of clearant.

28. (New claim) The apparatus of claim 27, wherein the contaminated dehydrant agent is purge dehydrant.

29. (New claim) The apparatus of claim 24, wherein the infiltrating medium comprises paraffin.

30. (New claim) The apparatus of claim 23, wherein the fluid flow selector may connect any of the containers to the processing chamber in any sequence.

31. (New claim) The apparatus of claim 30, wherein the fluid flow selector

comprises a rotary valve and wherein the control device selects the containers of clearant, contaminated dehydrant, dehydrant or aqueous fluid by setting the rotary valve.

32. (New claim) The apparatus of claim 30, wherein the apparatus automatically processes the specimen from the aqueous fluid to the infiltrating medium, and

wherein the control device controls the fluid flow selector to connect the processing chamber with the container of aqueous solution, the container of dehydrant agent, the container of clearant agent and the container of infiltrating medium, in order to automatically and sequentially process the sample.